

**AFIA FOAMING ANTI-BACTERIAL HAND CLEANER- benzalkonium chloride soap
National Chemical Laboratories, Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Listing of Afia Foaming Anti-Bacterial Hand Cleaner

Drug Facts

Active Ingredient. Purpose

Benzalkonium Chloride 0.13%.....Antimicrobial

USE

For hand washing to decrease bacteria on the skin

Uses

For hand washing to decrease bacteria on the skin

Warnings:

For external use only.

When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Directions

- Wet a hand. Pump one or two stokes of foam, into palm of hand.
- Rub thoroughly over all surfacesof both hands for 30 seconds
- Rinse hands and dry thoroughly.


Inactive ingredients

Water, Cetrimonium Chloride, Laurtrimonium Chloride, Dihydroxyethyl Cocamine Oxide, Cocamidopropyl PG-Dimonium Chloride Phosphate, Glycereth-2 Cocoate, Phenoxyethanol, Cocamidopropyl Hydroxysultaine, fragrance, Benzoic Acid, Methylisothiazolinone, FD&C yellow 5, FD&C blue 1

Warnings:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Afia Anti-Bacterial Foaming Hand Cleaner

| | | |
|--|----------------|---|
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AFIA FOAMING ANTI-BACTERIAL HAND CLEANER

benzalkonium chloride soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71023-046 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LAURTRIMONIUM CHLORIDE (UNII: A81MS10FIC) | |

| |
|---|
| CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP) |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) |
| DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5) |
| COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4) |
| GLYCERETH-2 COCOATE (UNII: JWM00VS7HC) |
| WATER (UNII: 059QF0KO0R) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W) |
| BENZOIC ACID (UNII: 8SKN0B0MIM) |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71023-046-57 | 1000 mL in 1 BAG; Type 0: Not a Combination Product | 05/08/2023 | |
| 2 | NDC:71023-046-29 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/08/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/08/2023 | |

Labeler - National Chemical Laboratories, Inc. (002289619)

Registrant - National Chemical Laboratories, Inc. (002289619)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------------|---------|-----------|------------------------|
| National Chemical Laboratories, Inc. | | 002289619 | manufacture(71023-046) |

Revised: 5/2023

National Chemical Laboratories, Inc.